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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/037,369 | 11/07/2001 | Basant Sharma | ORT-1531 | 6789 |

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| EXAMINER |
|---|
| MELLER, MICHAEL V |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1654 | |

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/037,369 | SHARMA ET AL. | |
| | Examiner | Art Unit | |
| | Michael V. Meller | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *7-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 1-6 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that group I and II do not place an undue burden on the examiner. This is not found persuasive because as stated in the previous office action the composition can be made by a materially distinct process such as genetic engineering.

The election of species is withdrawn in view of applicant's statement that the members of the erythropoietin family are expected to have similar activities and utilities when placed in the formulation of claim 1.

Thus, claims 7-19 are withdrawn from further consideration by the examiner.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition containing erythropoitein, sodium phosphate buffer, NaCl, KCl or glycine, and CMC (carboxymethyl cellulose), does not

reasonably provide enablement for any and all pH buffering agents and tonicity agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification as filed, is enabled for a composition containing erythropoitein, sodium phosphate buffer, NaCl, KCl or glycine, and CMC (carboxymethyl cellulose), but is not enabled for any and all pH buffering agents and tonicity agents.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all pH buffering agents and tonicity agents to see if they would work in the claimed invention.

Applicant has only shown in their specification examples where erythropoitein, sodium phosphate buffer, NaCl, KCl or glycine, and CMC (carboxymethyl cellulose) are used and not any and all pH buffering agents and tonicity agents, knowing only these few components one of ordinary skill in the art could not be expected to know which of the thousands of pH buffering agents and tonicity agents would work in the claimed composition. With only knowing this one source it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given one particular composition. There are thousands of possible pH buffering and tonicity agents in the field of biotechnology and one of ordinary skill in the art would not know which others to pick of the thousands of possibilities available to working this specific invention in the highly unpredictable field of biotechnology.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ritchey et al.

The references teaches erythropoietin, CMC and buffers to provide pH in the range claimed and other agents.

The pH of the composition is inherent to that composition.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 rejected under 35 U.S.C. 103(a) as being unpatentable over Sytkowski '446, Chiba et al. '801, Chiba et al. '624, Woog et al., Sytkowski et al. '758, or Sytkowski et al. '272 taken with Casas, Yamada et al. or Ishikawa et al.

· Sytkowski '446, Chiba et al. '801, Chiba et al. '624, Woog et al., Sytkowski et al. '758, and Sytkowski et al. '272 all teach a pharmaceutical composition containing erythropoitein, sodium phosphate and sodium chloride.

Casas, Yamada et al. and Ishikawa et al. all teach using CMC in pharmaceutical compositions.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman,* 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

To use any one of the specific types of erythropoietin is obvious as was admitted by applicants in their latest response.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchey et al. taken with Sytkowski '446, Chiba et al. '801, Chiba et al. '624, Woog et al., Sytkowski et al. '758, or Sytkowski et al. '272.

Ritchey teaches using CMC and erythropoietin together in a composition.

Sytkowski '446, Chiba et al. '801, Chiba et al. '624, Woog et al., Sytkowski et al. '758, and Sytkowski et al. '272 all teach a pharmaceutical composition containing erythropoitein, sodium phosphate and sodium chloride.

It would have been obvious to add sodium phosphate and sodium chloride to the composition of Ritchey since the secondary references make it clear that such buffers and additives are routinely added to pharmaceutical compositions containing erythropoietin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Michael V. Meller
Primary Examiner
Art Unit 1654

MVM
May 16, 2003